



Food and Drug Administration
10903 New Hampshire Avenue
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September 30, 2014

Reflow Medical
Ms. Rebecca Pine
VP of Regulatory/Clinical Affairs & Quality Assurance
1003 Calle Sombra
San Clemente, CA 92673 US

Re: K141547
Trade/Device Name: Wingman Extendable Tip Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 30, 2014
Received: July 02, 2014

Dear Ms. Pine,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5

Indications for Use Statement

5. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
510(k) Number (if known)	
Device Name Wingman Extendable Tip Support Catheter	
Indications for Use (Describe) The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.	
Type of Use (Select one or both, as applicable)	
<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.	
FOR FDA USE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
This section applies only to requirements of the Paperwork Reduction Act of 1995. *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.* The burden time for this collection of information is estimated to average 70 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."</i>	

510(k) Summary

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This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: ReFlow Medical
DATE PREPARED: June 10, 2014
CONTACT PERSON: Rebecca K Pine
ReFlow Medical
1003 Calle Sombra
San Clemente, CA 92673
Phone: (760) 809.5178
TRADE NAME: Wingman Extendable Tip Support Catheter
COMMON NAME: Guide Catheter
CLASSIFICATION NAME: Percutaneous Catheter
DEVICE CLASSIFICATION: Class 2, per 21 CFR 870.1250
PRODUCT CODE DQY

PREDICATE DEVICES: Wingman Extendable Support Catheter (K132420)

Substantially Equivalent To:

The modified Wingman Extendable Tip Support Catheter is substantially equivalent in intended use, principal of operation and technological characteristics to the Wingman Extendable Support Catheter cleared under premarket notification K132420.

Description of the Device Subject to Premarket Notification:

The Wingman Extendable Tip Support Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The device consists of a support catheter, with a concealed radiopaque beveled guide-tip, and activating handle. The through-lumen of the device can serve as a conduit for the delivery of diagnostic and therapeutic agents. The Wingman Extendable Tip Support Catheter product line is being extended to add a .035 diameter device configuration.

Indication for Use:

The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or

510(k) Summary

diagnostic/therapeutic agents.

Technical Characteristics:

The modified Wingman Extendable Tip Support Catheter has similar physical and technical characteristics to the predicate device. The modified Wingman and predicate Wingman devices differ in the following:

- Product line extension; new diameter: .035

Performance Data:

All necessary testing has been performed for the Wingman Extendable Tip Support Catheter to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Simulated Use
- Tensile Strength
- Torque
- Pressure Test
- Coating verification
- Corrosion Test
- Dimensional verification and visual inspections
- Sterilization Validation
- Biocompatibility

The modified Wingman Extendable Tip Support Catheter met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:

The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified Wingman Extendable Tip Support Catheter is determined by ReFlow Medical, to be substantially equivalent to the Wingman Extendable Tip Support Catheter (K132420).